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SHARING EXPERTISE

PEPCAD IV – Paclitaxel-Eluting Balloon Angioplasty and Cobalt-Chromium Stents vs. Conventional Angioplasty and Paclitaxel-Eluting Stents in the Treatment of Native Coronary Artery Stenoses of Diabetic Patients

B. Braun Melsungen AG, Vascular Systems, Clinical Science

Objective: The aim of the study is to compare the efficacy of Paclitaxel-eluting PTCA-balloon dilation (SeQuent™ Please) followed by cobalt-chromium stent (Coroflex™ Blue) deployment versus Paclitaxel-eluting stent (Taxus™ Liberté™) deployment in the treatment of de-novo stenoses in native coronary arteries (reference diameter: ≥2.5 mm and ≤3.5 mm, length of stenosis ≥ 10 mm ≤ 20 mm) of patients with diabetes mellitus for ≥ 3 years for procedural success and preservation of vessel patency.

Study Design: This study is a prospective, randomized, multi-center, two armed phase-II pilot study conducted in Malaysia and Thailand.

Number of patients: 128 diabetes mellitus patients shall complete the study per protocol after random assignment to either of the treatment groups on the order of 20 to 50 patients per center.

Selection Criteria: Diabetes mellitus patients with stable or selected forms of unstable angina or documented ischemia due to a de-novo stenosis in a native coronary artery will be enrolled. Vessels may not supply an entirely infarcted myocardial area.

Primary Variable: Late lumen loss at 9 months

Secondary Variables: Procedural success; Occurrence of acute (up to 48 hours), subacute (up to 30 days), and late thrombosis; 30-day MACE rate; Percent in-stent stenosis at 9 months; Percent in-segment stenosis at 9 months; In-stent late loss index at 9 months; Angiographic binary in-stent stenosis rate at 9 months; In-segment late loss index at 9 months; Angiographic binary in-segment stenosis rate at 9 months; Acute and cumulative MACE rate at 9 months; Cumulative MACE rate after 2 years; Indication for premature follow-up; Type of recurrence (Mehran-Classification); Target vessel failure

Scheduled Follow-up: Clinical and angiographic follow-up scheduled at 9 months and 3-year MACE for all patients

Principle investigator: Dr. Rosli Mohd Ali, National Heart Institute Kuala Lumpur, Malaysia

Status: Recruiting

Publication: -

Sponsor: B. Braun Melsungen AG

Register: http://clinicaltrials.gov/ct2/show/NCT00462631